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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/073,899	03/28/2011	Ze'ev Shaked	6229-01302	8735

35690 7590 12/12/2016

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ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
12/12/2016	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ZE'EV SHAKED, KLAUS NICKISCH, JAMES DiNUNZIO, FENG ZHANG, and MARCELO OMELCZUK.[1]

Appeal 2015-007854
Application 13/073,899
Technology Center 1600

Before ULRIKE W. JENKS, JOHN E. SCHNEIDER, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to an intravaginal drug delivery device which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

The present invention is directed to an intravaginal drug delivery device which releases "one or more active substances in a substantially constant ratio over a prolonged period of time." Spec. 1. The drug delivery

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[1] Appellants identify the Real Party in Interest as Evestra, Inc. Appeal Br. 1.

device comprises an uncoated thermoplastic matrix and one or more hormones, such as progestin, dispersed in the matrix. Spec. 6. The device can deliver an effective amount of the hormone for up to thirty days. Spec. 3.

Claims 1, 2, 5, 14, 34, and 94–98 are on appeal. Claim 1 is illustrative and reads as follows:

> 1. An intravaginal drug delivery device comprising:
> an intravaginal ring that comprises a thermoplastic matrix, one or more hydrophilic materials, a progestin, and an estrogen compound; and
> wherein the thermoplastic matrix comprises an ethylene vinyl acetate copolymer; and
> wherein the progestin and the estrogen compound are distributed homogenously throughout the intravaginal ring;
> wherein the intravaginal ring does not include a coating on the outer surface of the thermoplastic matrix that would alter the release rate of the progestin and the estrogen compound from the thermoplastic matrix during use;
> wherein the intravaginal ring has an average release rate of progestin of about 0.05 to about 5 mg per 24 hours for 4 days up to about 30 days after administration to a female subject, and wherein the intravaginal ring has an average release rate of the estrogen compound of about 0.01 to about 0.1 mg per 24 hours for 4 days up to about 30 days after administration to a female subject; and
> wherein the release rate of the progestin and the estrogen compound does not vary by an amount greater than about 30% of the amount released per 24 hours for 4 days up to about 30 days.

The claims stand rejected as follows:

Claims 1, 2, 5, 14, 34, and 94–98 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Woolfson[2] in view of Ron[3].

THE REJECTION UNDER 35 U.S.C. § 103(a)

Issue

In rejecting the pending claims as obvious the Examiner finds that Woolfson teaches an intravaginal drug delivery device in the shape of a ring that comprises a thermoplastic matrix, one or more hydrophilic materials, and estrogen and progestin compounds. Final Act. 4–5. The Examiner also finds that the device in Woolfson does not include a coating on the outer surface of the ring which would alter the release rate of the progestin and estrogen compounds. *Id.* The Examiner finds that while Woolfson does not teach the amount of drugs released per 24 hours, Ron provides the necessary teaching. Final Act. 6. The Examiner finds that Ron teaches an intravaginal ring "wherein the device releases 100 μg/day estradiol and 6 mg/day progesterone. (cl. 55, 56 (7 days and 30 days); [0165] (21 days each, 100 mcg/day estradiol, 6 mg/day progesterone))." *Id.* The Examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a release rate of, for example, 100 mcg/day estradiol and 6 mg/day progesterone, as suggested by Woolfson et al. and Ron et al., and produce the instant invention." *Id.*

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[2] Woolfson et al., US 2009/0004246 A1, published Jan. 1, 2009 ("Woolfson").
[3] Ron et al., US 2011/0280922 A1 published Nov. 17, 2011 ("Ron").

Appellants contend that the present invention calls for the hydrophilic materials to reduce the release rate of the hormones contained in the ring in contrast with the teachings of Woolfson which call for the hydrophilic material to increase the release rate. Appeal Br. 5–7. Appellants argue that one skilled in the art would not look to Woolfson for guidance as to how to lower the release rate as Woolfson is directed to the achieving the opposite. *Id.* Appellants argue that Ron does not cure the deficiencies of Woolfson as Ron does not teach the use of a hydrophilic material to control the release of a hydrophobic agent such as estrogen or progestin hormones. Appeal Br. 8–9.

The issue is whether the Examiner has established by a preponderance of the evidence that claims 1, 2, 5, 14, 34, and 94–98 would have been obvious over Woolfson combined with Ron under 35 U.S.C. § 103(a).

Findings of Fact

We adopt as our own the Examiner's findings and analysis. The following findings are included for emphasis and reference convenience.

FF1. Woolfson discloses an intravaginal device for the administration of pharmaceutically active drugs or agents. Woolfson ¶ 1.

FF2. The intravaginal devices of Woolfson are typically in the form of an intravaginal ring. Woolfson ¶ 57.

FF3. The rings of Woolfson comprise a polymeric hydrophobic carrier material such as poly(ethylene-co-vinyl acetate). Woolfson ¶¶ 59–60.

FF4. The rings of Woolfson also contain a water-soluble release enhancer such as sugars, sugar alcohols and polyethylene glycol. Woolfson ¶ 45.

FF5. The rings of Woolfson may not have a sheath. Woolfson ¶ 58.

FF6. Woolfson teaches that the rings can include a progestin and an estrogen compound for use as a contraceptive or a hormone replacement. Woolfson ¶¶ 66 and 67.

FF7. Woolfson teaches that the release rate of the active components is controlled by "the ratio of the hydrophobic insert carrier material to the water-soluble release enhancer . . . It is this feature that permits sustained release profiles to be achieved." Woolfson ¶ 49.

FF8. Ron discloses a vaginal delivery system for delivery of one or more active agents. Ron ¶ 7.

FF9. The delivery system of Ron can be a unitary segment in the shape of a ring and can comprise an ethylene vinyl acetate copolymer. Ron ¶ 65.

FF10. The active agents delivered by the system of Ron can include progestins and estrogens. Ron ¶ 83.

FF11. Ron teaches that the delivery system can be designed to deliver 100 μg estradiol (an estrogen) and 6 mg of progesterone (a progestin) per day over a 21-day period. Ron ¶ 165.

Principles of Law

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." *In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991).

"In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007).

Analysis

Claim 1 is representative of the rejected claims and is directed to an intravaginal delivery device comprising an ethylene vinyl acetate copolymer and a hydrophilic material for the delivery of an estrogen compound and progestin.

We agree with the Examiner that the subject matter of claim 1 would have been obvious to one skilled in the art at the time the invention was made. Woolfson discloses an intravaginal delivery device in the shape of a ring which comprises an ethylene vinyl acetate copolymer and a hydrophilic material. FF 1–4. Woolfson teaches that the delivery device may not have an outer sheath or layer which would affect the delivery of the active agents in the device. FF5. The devices in Woolfson can be used to deliver estrogen compounds and progestins. FF6. Ron discloses an intravaginal delivery device which can be designed to release 100 μg estradiol (an estrogen) and 6 mg of progesterone (a progestin) per day over a 21 day period. FF11.

Substantial evidence supports the Examiner's conclusion that the claimed device would have been obvious.

> Appellants argue that neither of the references
>
> teach or suggest the use of a hydrophilic material in a hydrophobic matrix (ethylene vinyl acetate) to reduce the release rates of estrogens and progestins from the hydrophobic matrix. In fact, both Woolfson and Ron teach the need to enhance or increase the release rate of compounds from a hydrophobic matrix. Applicant submits that, without the benefit of the teachings of Applicant's specification, a person of ordinary skill in the art would not be motivated by the cited art (i.e., Woolfson and Ron) to modify the product of Woolfson by adding hydrophilic compounds to a hydrophobic matrix with the expectation of producing an extended release product.

Appeal Br. 9.

We are unpersuaded. To begin we note that the claims do not recite the hydrophilic material decreases the release of estrogen compounds and progestins. Appeal Br. 17 (Claims Appendix). In addition, Woolfson specifically teaches that by altering the ratios of the hydrophilic material and the base polymer the release rates of the active agents can be controlled allowing for the creation of a sustained release profile. FF7. Thus the combination of materials in Woolfson achieves the same result as the present invention – sustained release of estrogens and progestins over time. We agree with the Examiner that one skilled in the art would have been motivated to combine the teachings of Woolfson and Ron to produce a sustained release ring device which releases progestins and estrogens in the amounts called for in the instant claims.

Claims 2, 5 and 95

With respect to claims 2, 5, and 95, Appellants argue that neither of the references teach or suggest the specific combination of a drug delivery device comprising ethylene vinyl acetate copolymer matrix containing etonogestrel and estrogen or a device wherein the estrogen compound is ethinylestradiol. Appeal Br. 9–10, and 15. We are unpersuaded. While neither reference teaches a single combination of all the recited elements, the references, in combination, teach all the elements of the claims including the use of etonogestrel as the progestin compound, Woolfson ¶ 67, and ethinylestradiol, Woolfson ¶¶ 67 and 68.

Claim 34

While claim 34 was argued separately, the arguments presented are essentially the same as the arguments presented for claim 1. The arguments are not persuasive for the reasons stated above.

Claim 94

In addition to the arguments Appellants presented in connection with claims 1 and 34, Appellants argue that the Examiner conceded that Woolfson does not teach the extended release properties of the claimed device and that Ron does not make up for those deficiencies. Appeal Br. 13–14. We are not persuaded. The Examiner specifically pointed out the sections of Woolfson that taught the extended release of progestin and estrogen compounds. Ans. 18. Moreover, as discussed above, Woolfson specifically teaches creation of a sustained release profile. FF7.

Conclusion of Law

We conclude that the Examiner has established by a preponderance of the evidence that claims 1, 2, 5, 34 and 94 would have been unpatentable over Woolfson combined with Ron under 35 U.S.C. § 103(a).

Claims 14 and 95–98 have not been argued separately and therefore fall with claims 1 and 94. 37 C.F.R. § 41.37(c)(1)(iv).

SUMMARY

We affirm the rejection based on 35 U.S.C. § 103(a).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED